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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/749,719	12/31/2003	Victor I. Chomenky	1004.009	8841
7590	10/05/2006		EXAMINER	
Craig Gregersen P.O. Box 386353 Bloomington, MN 55438			VRETTAKOS, PETER J	
			ART UNIT	PAPER NUMBER
			3739	

DATE MAILED: 10/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/749,719	CHORNENKY ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Peter J. Vrettakos	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 7-18-06.
- 2a) This action is FINAL.                  2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-6 is/are rejected.
- 7) Claim(s) 4-6 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |                                                                                      |                                                                   |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____.                                     |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____.                                                         | 6) <input type="checkbox"/> Other: _____.                         |

## **DETAILED ACTION**

The application is published application number: 2004/0158302. The publication is classified in US 606/41.

The effective filing date of this application is 5-10-2000.

Pending claims as of 9-22-06 are 1-6.

The claim language is replete with intended use language, which provides little patentable weight to apparatus claims. This is further addressed below.

The action is **final** as necessitated by amendment.

### ***Claim Objections***

Claims 4-6 are objected to because of the following informalities: the word "for" repeats itself in line 8. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schaer (5,782,760) in view of Gunderson et al. (5,601,087).

Schaer provides an over-the-wire-catheter suggesting use with a guidewire, and Gunderson provides a guidewire with an optical fiber suggesting use with an over-the-wire catheter.

Note: a recitation of the **intended use** of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

The combination of the two patents makes obvious:

1. An apparatus for treatment of cerebral aneurysms and AVMs (intended use), comprising:
  - a laser (Gunderson 30) generating ultraviolet radiation;
  - a steerable guide wire (Gunderson 12 and 14) housing an optical fiber (20) including proximal and distal fiber ends, said fiber (20) extended extending from (see figure 1) the proximal to the distal end of the guide wire (12 and 14) and coupled at said proximal fiber end (see figure 4) to the laser, such optical fiber providing a transmissive pathway for the laser-generated ultraviolet radiation to said optical fiber distal end for emission therefrom (col. 6:25-38), and;
  - an over-the-wire catheter (Schaer, numerous embodiments; figures 3, 5, 11, 15) including proximal and distal catheter ends and further including an occlusive balloon (43 in figure 11) and a micro tube (62 in figure 15) adapted for delivery of saline

("cooling fluid", see col. 7:1-11) into an artery (intended use) distally to the catheter distal end for displacing blood from the aneurysm or AVM (intended use) and clearing the optical field in front of the distal end of the optical fiber, said guide wire being slidably received within said catheter (this movability of the guide wire is permitted by definition of an "over-the-wire catheter") and being reciprocably movable (this movability of the guide wire is permitted by definition of an "over-the-wire catheter") therein such that said optical fiber distal end can be extended beyond said catheter distal end such that said ultraviolet radiation emitting optical fiber distal end is not obstructed by said catheter (any properly dimensioned guidewire used with Schaer would be permitted to extend beyond the distal end of Schaer as a result of Schaer's open distal port 34 in figure 1); wherein said apparatus delivers ultraviolet radiation to the inside surface of the aneurysm or AVM (intended use) so as to cause the death of a sufficient number of the endothelial cells (intended use) on the irradiated surface of the aneurysm such that a mural thrombus is formed and the aneurysm is strengthened against rupture (intended use).

2. The apparatus of claim 1 wherein the laser generates [UV] ultraviolet radiation in the range of 240 to 280 nanometers, corresponding to maximum [UV] ultraviolet absorption in DNA. Gunderson discloses numerous wavelengths (col. 2:25-30, col. 9:55-63) outside the claimed wavelengths; however see MPEP § 2144.05 II A regarding optimization and routine experimentation.

3. The apparatus of claim 1 wherein said fiber distal end is coupled to an optical tip adapted for scattering [UV] ultraviolet radiation in substantially semispherical (see the semispherical bead of epoxy 22 in Gunderson figure 1 as well as col. 6:25-38) directions for substantially complete irradiation of the inner surface of the aneurysm. Also see MPEP § 2144.04 IV B regarding Applicant changes in shape in light of the prior art.

4. An apparatus for treatment of aneurysms (intended use) comprising:

- a laser (Gunderson 30) generating ultraviolet radiation;
- a steerable guide wire (Gunderson 12 and 14) including proximal and distal wire ends;
- an over-the-wire catheter (Schaer, numerous embodiments; figures 3, 5, 11, 15) including a wall and at least one optical fiber (20) including proximal and distal fiber ends disposed within said catheter wall, wherein said proximal fiber end is coupled to the laser and said distal fiber end is extended to said distal end of said catheter (all addressed above), said catheter including a central passage (34) for receiving said guide wire (Gunderson 12 and 14) and for delivery of saline (see Schaer figure 5) into an artery for displacing blood from the aneurysm or AVM (intended use) and clearing the optical field in front of the distal end of the optical fiber; wherein said apparatus delivers ultraviolet radiation to the inside surface of the aneurysm so as to cause the death of a sufficient number of the endothelial cells on the irradiated surface (intended

use) of the aneurysm such that a mural thrombus is formed (intended use) and the aneurysm is strengthened against rupture (intended use).

5. The apparatus of claim 4, in which the laser generates [UV] ultraviolet radiation in the range of 240 to 280 nanometers, corresponding to maximum [UV] ultraviolet absorption in DNA. Gunderson discloses numerous wavelengths (col. 2:25-30, col. 9:55-63) outside the claimed wavelengths; however see MPEP § 2144.05 IIA regarding optimization and routine experimentation.
  
6. (Currently amended) The apparatus of claim 4 and including a plurality of optical fibers each including proximal and distal fiber ends, wherein at least one of said distal fiber ends is coupled to an optical tip adapted for scattering [UV] ultraviolet radiation in different substantially semispherical (see the semispherical bead of epoxy 22 in Gunderson figure 1 as well as col. 6:25-38) directions for substantially complete irradiation of the inner surface of the aneurysm. Also see MPEP § 2144.04 IV B regarding Applicant changes in shape in light of the prior art.

Note: interchangeability of elements from different embodiments in the same patent is seamless unless the substitution renders an embodiment inoperable.

Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to combine the Schaer over-the-wire catheter with the Gunderson guide wire

the motivation being to combine what both patents explicitly suggest (Schaer col. 7:10 and Gunderson col. 4:34-36).

### ***Double Patenting***

The **nonstatutory** double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed **terminal disclaimer** in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-6 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of **U.S. Patent No. 6,692,486**. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims disclose the apparatus described in the patented method claims.

***Response to Arguments***

Applicant's arguments with respect to claims 1-6 have been considered but are moot in view of the new ground(s) of rejection. Prior rejections (excluding the maintained Double Patenting rejection) are obviated through amendments.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J. Vrettakos whose telephone number is 571-272-4775. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pete Vrettakos  
September 23, 2006

*PV*

*Roy D. Gibson*  
ROY D. GIBSON  
PRIMARY EXAMINER